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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/769,582

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Niall Duffy

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER

APANIUS, MICHAEL

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/769,582

Applicant(s)

DUFFY, NIALL

Examiner

Michael Apanius

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Drawings

1. Figures 1-4 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g).
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "310" in figure 4.
3. The drawings are further objected to because it appears that "100" in figure 2 should be --100'-- to be consistent with the specification.
4. The drawings are even further objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "guidewire removal tool 60" at paragraph 42, line 5.
5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

Art Unit: 3736

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The disclosure is objected to because of the following informalities: at paragraph 34, line 13, it appears that "inflation lumen 58" should be either --inflation lumen 54-- or --guidewire lumen 58-- and at paragraph 37, line 3, it appears that "catheter 100" should be --catheter 50-- and at paragraph 44, line 7, it appears that "from a" should be deleted. Appropriate correction is required.

Claim Objections

7. Claims 13-19 and 24 are objected to because of the following informalities: at claim 13, line 4, it appears that "a opening" should be --an opening--; and it appears that claim 16 should depend from claim 15, not claim 14; and at claim 24, line 2, "the wheel" lacks proper antecedent basis in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3736

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 13-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Greelis et al. (US 5,346,498). Greelis discloses an apparatus for advancing and retracting elongated, flexible medical instruments, such as a catheter and a guidewire (column 8, lines 1-4), in a patient, the apparatus comprising: an elongate housing (61 in figure 2) having a proximal end and a distal end; an opening (through 59 and 73) formed through the housing from the proximal end to the distal end and adapted to house elongated, flexible medical instruments; a wheel port (figure 11) formed in the housing between the proximal and distal ends and in communication with the opening; and a wheel (83C in figure 11) secured in the wheel port and radially extending into the opening to engage with an elongated, flexible instrument. In regards to claim 14, the wheel port includes slots (93C), and the wheel includes an axle (91C) that is rotatably secured in the slots. In regards to claim 15, the wheel includes a large diameter portion (the portion comprising the two upward facing regions (209, 215) and the portion there between as shown in figure 12) and two small diameter portions (the portions on each side of the large diameter portion) flanking the large diameter portion. In regards to claim 16, the large diameter portion has a circumferential concave surface (103C). In regards to claim 17, each of the small diameter portions has a circumferential concave

Art Unit: 3736

surface (213 and the notch portion on the left). In regards to claim 18, the large diameter portion is approximately centered between the small diameter portions. In regards to claim 19, wheel port is formed proximate to the housing distal end.

10. Claims 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuqua (US 4,601,713). Fuqua discloses a catheter (figures 11 and 12), comprising: an elongate shaft having an exterior surface, a proximal end, and a distal end; a first lumen (15 in figure 11) extending through the shaft from the shaft proximal end to the shaft distal end, and sized to receive a guidewire; and a guideway (narrow area shown at bottom of figure 11) extending from the shaft proximal end to the shaft distal end, and enabling transverse access from the shaft exterior surface to the first lumen. In regards to claim 21, the catheter further comprises a second lumen (area shown around the edges of the folded catheter that is partially occupied by stylet 12) extending through the shaft from the shaft proximal end to the shaft distal end and having a nearly annular cross sectional area that almost entirely surrounds the first lumen.

11. Claim 20 is rejected under 35 U.S.C. 102(e) as being anticipated by Windheuser et al. (US 6,606,515). Windheuser discloses a catheter (figure 1E), comprising: an elongate shaft having an exterior surface, a proximal end, and a distal end; a first lumen (43) extending through the shaft from the shaft proximal end to the shaft distal end, and sized to receive a guidewire; and a guideway (narrow opening at top of figure 1E)

Art Unit: 3736

extending from the shaft proximal end to the shaft distal end, and enabling transverse access from the shaft exterior surface to the first lumen.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luther (US 4,401,433) in view of Fuqua (US 4,601,713).

14. Luther discloses a catheter (30), comprising: an elongate shaft having an exterior surface, a proximal end, and a distal end; a first lumen (see the central area of figure 2B and 13F in figure 6) extending through the shaft, and sized to receive a guidewire; and a guideway (narrow area shown at top of 13F) enabling transverse access from the shaft exterior surface to the first lumen. In regards to claim 21, the catheter further comprises a second lumen (area shown around the edges of the folded catheter) having a nearly annular cross sectional area that almost entirely surrounds the first lumen. In regards to claim 22, the lumens are formed from a single wall having substantially uniform thickness. In regards to claim 23, the single wall includes two approximately parallel segments that together define the catheter guideway. In regards to claim 24, the two parallel segments are capable of being flexibly spaced apart when an object is forced between the two parallel segments. However, Luther does not expressly disclose that

Art Unit: 3736

the shape defined in the claims extends from the shaft proximal end to the shaft distal end.

15. Fuqua teaches using a stylet (12) to releasably hold a catheter in a folded shape for the purpose of allowing controlled unfolding of the catheter (i.e. column 9, lines 32-36) and to vary the rigidity of the catheter (paragraph bridging columns 6 and 7). Note that the use of the stylet would allow the entire length of the catheter to be maintained in a folded position.

16. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a stylet as taught by Fuqua with the catheter of Luther in order to allow controlled unfolding of the catheter and to vary the rigidity of the catheter.

17. Claims 1, 2, and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuqua (US 4,601,713) in view of Greelis et al. (US 5,346,498). Fuqua discloses a catheter as noted above. However, Fuqua does not expressly disclose a catheter advancing and retracting apparatus as set forth in claim 1. Greelis teaches a catheter advancing and retracting apparatus as noted above for the purpose of simplifying catheter positioning (column 2, lines 23-25) and to allow single-handed operation (column 2, lines 44-48). Note that the wheel of Greelis is sized to extend into a flexible catheter guideway. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used the catheter advancing and retracting

Art Unit: 3736

apparatus as taught by Greelis with the catheter of Fuqua in order to simplify catheter positioning and to allow single-handed operation.

18. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luther (US 4,401,433) as modified by Fuqua (US 4,601,713) as applied to claims 20-24 above, and further in view of Greelis et al. (US 5,346,498). Luther as modified by Fuqua teaches a catheter as noted above. Furthermore, Luther teaches a catheter advancing and retracting apparatus (10) but does not expressly disclose the specific limitations recited in claim 1. Greelis teaches a catheter advancing and retracting apparatus as noted above for the purpose of simplifying catheter positioning (column 2, lines 23-25) and to allow single-handed operation (column 2, lines 44-48). Note that the wheel of Greelis is sized to extend into a flexible catheter guideway. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used the catheter advancing and retracting apparatus as taught by Greelis with the catheter of Luther as modified by Fuqua in order to simplify catheter positioning and to allow single-handed operation.

19. Claims 1 and 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Windheuser et al. (US 6,606,515) in view of Greelis et al. (US 5,346,498). Windheuser discloses a catheter as noted above and a guidewire removal tool (figure 19), comprising a substantially cylindrical main body (812) sized to be received by the first lumen and having a chamfered leading edge (column 22, lines 59-62). Note that

Art Unit: 3736

although the guidewire removal tool is disclosed as functioning as a guidewire re-insertion tool, it is also capable of being used oppositely to raise the guidewire out of the first lumen through the guideway. However, Windheuser does not expressly disclose a catheter advancing and retracting apparatus as set forth in claim 1. Greelis teaches a catheter advancing and retracting apparatus as noted above for the purpose of simplifying catheter positioning (column 2, lines 23-25) and to allow single-handed operation (column 2, lines 44-48). Note that the wheel of Greelis is sized to extend into a flexible catheter guideway. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used the catheter advancing and retracting apparatus as taught by Greelis with the catheter of Windheuser in order to simplify catheter positioning and to allow single-handed operation.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

Art Unit: 3736

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

21. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

22. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 20-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 12-15 of copending Application No. 10/903,802. Although the conflicting claims are not identical, they are not patentably distinct from each other because copending claims 1 and 12-15 clearly recite all of the limitations of instant claims 20-24, respectfully. Therefore, the instant claims are fully "anticipated" by the copending claims and are not patentably distinct. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion


24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
- a. US 3,835,854 discloses a catheter advancing device with nip rollers.
 - b. US 4,710,181 discloses a variable diameter catheter.
 - c. US 4,988,356 discloses a catheter and guidewire exchange system.
 - d. US 5,195,978 discloses a rapid exchange over-the-wire catheter with breakaway feature.
 - e. US 5,318,541 discloses an apparatus for catheter exchange in vascular dilatation.
 - f. US 6,171,234 discloses an imaging gore loading tool.
 - g. US 6,290,675 discloses a device for withdrawing a catheter.
 - h. US 6,726,675 discloses a remote control catheterization.
 - i. US 6,752,800 discloses a catheter handle for controlling the advancement of a guide wire.
 - j. US 2005/0004579 discloses a computer-assisted manipulation of catheters and guide wires.
25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8:30am-5pm.

Art Unit: 3736

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA


MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700